DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (714) 798-7600

HCT

M3171A

WARNING LETTER

March 1, 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Jacob Barrett, Owner
The Source d.b.a. Seafood Source
3131 University Avenue
San Diego, CA 92104

W/L 24-9

Dear Mr. Barrett:

On October 21 & 22, 1998, an Investigator from the Food & Drug Administration (FDA) conducted an inspection of your firm, located at 3131 University Ave., San Diego, California. At the conclusion of the inspection Donald B. Drevna, Account Executive, was presented with Form FDA 483 listing significant deviations from Title 21 of the Code of Federal Regulations (21 CFR) part 123 - Hazard Analysis Critical Control Point (HACCP) Regulation. A copy of that Form FDA-483 is enclosed for your review.

Additional information was gathered by our Investigator during a subsequent inspection of your firm on November 30, 1998, during which time Michael W. Burns, Director of Seafood Sales was presented with Form FDA-483 listing significant deviations from Title 21 of the Code of Federal Regulations (21 CFR) part 110 - Current Good Manufacturing Practice in Manufacturing, Packing, and Holding Human Food (GMPs).

Based on our inspections, we have determined that hot smoked fishery products processed at your facility are adulterated within the meaning of Section 402(a)(4) of the Food, Drug and Cosmetic Act (the Act). Specifically, our investigator found the following deficiencies, related to hot smoked, vacuum packaged or air packaged salmon and other fish, stored and sold as refrigerated products:

1. Your firm has not written or implemented a HACCP plan covering the hot smoking process used in the facility. These deficiencies were brought to your attention during the previous inspection of your facility in March of 1998, and reiterated in a letter sent to your firm dated June 4, 1998.

Your firm must prepare and fully implement a HACCP plan for your hot smoked fish operations conducted at your firm. Per 21 CFR 123.6, this plan must include: 1) food safety hazards that are reasonably likely to occur; 2) critical control points (CCPs) for each identified food safety hazard; 3) critical limits that must be met at each of the CCPs; 4) procedures, and frequency thereof, that will be used to monitor the CCPs to ensure the critical limits are met; 5) predetermined corrective action plans, if any; 6) verification procedures and frequency thereof; and 7) a recordkeeping system that documents monitoring of the CCPs.

Required per 21 CFR 123.16, the HACCP plan for smoked fishery products shall also demonstrate how you controlling the food safety hazard associated with the formation of toxin by *Clostridium botulinum* for at least as long as the shelf life of the product under normal and moderate abuse conditions. One way to do this is to have a documented scientific study showing that your firm's smoked salmon process will control the hazard of *Clostridium botulinum.* A study should include analytical testing of a representative number of finished products is needed to show any process parameters that you have set up in your firm's HACCP plan are sufficient to prevent *Clostridium botulinum* growth and toxin formation on a consistent basis. In addition, the inspection revealed that the smoking chamber used in your firm may not be of adequate design to ensure that products being smoked achieve a proper heat treatment throughout the chamber. No heat penetration studies have been performed, and your firm has no data to show that your cooking time, heating source, and in-process procedure are sufficient to eliminate pathogens.

2. Your firm is not monitoring the eight key areas of sanitation as required in the HACCP regulation. 21 CFR 123.11(b) and (c) require that you monitor and record the monitoring and corrective action related to these key areas of sanitation. During the previous inspection in March of 1998, similar monitoring deficiencies were brought to your attention, however it does not appear that your firm has made any effort to begin this monitoring.

3. The product Tuna Dip is misbranded within the meaning of 403(i)(2) of the Act in that it contains a multi-component ingredient, [redacted] and the ingredients of [redacted] are not listed on the label. You may declare [redacted] followed by a parenthetical listing of the ingredients of [redacted] Or you may list each of the ingredients of [redacted] individually, among the other ingredients, in a descending order of predominance.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice, such as seizure or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations and to prevent their

recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Other Issues:

The above labeling violation is not meant to be an all-inclusive list of deficiencies on your labels. Other labeling deficiencies can subject the food to legal action. It is your responsibility to assure that all of your products are labeled in compliance with applicable statutes enforced by FDA. For example, during the 10/21,22/98 inspection of your facility, our investigator collected a label used for your hot smoked tuna product. It was observed that your firm was using a label for another product manufactured at the facility, "Tuna Dip". Although the word "Dip" was observed being inked out on these finished product labels, the ingredient statement was not amended to include only ingredients for the smoked tuna, thereby misbranding the product under 403 (a)(1) of the Act, in that the label bears false and misleading information.

For all of your refrigerated and/or frozen products, we would like to emphasize that their respective labels should include a statement indicating the need for refrigeration by the consumer. Current FDA labeling policy for foods similar to those produced at your facility strongly urges that you prominently label each product with the statement: "**IMPORTANT Must Be Kept Refrigerated To Maintain Safety.**" A copy of 2/24/97 Federal Register document "Guidance on Labeling of Foods That Need Refrigeration by Consumers" is enclosed for your review.

Aforementioned HACCP deficiencies (items 1 and 2) are not meant to be an all-inclusive list of deficiencies in your facility. Other products handled by your firm appear to also need HACCP controls in place, including live shellfish, refrigerated "dip" products such as "Tuna Dip", and fresh or frozen scombroid species such as mahi-mahi. A separate hazard analysis must be performed for these species, per 21 CFR 123.6 (a), and a HACCP plan must be written if hazards are present which are reasonably likely to occur. It is your responsibility to assure that all of your products are covered by HACCP plans if needed, and that these plans are implemented properly.

Enclosed is a Report of Sample Analysis (Form FDA-1551). Your firm has already received this document, however we are including this for discussion purposes. As detailed in the report, the two physical samples collected during the 10/21,22/98 inspection, consisting of smoked tuna (Sample # 29791), and smoked yellowtail (Sample # 29792), found water phase salt levels consistently below 3.5%, and averaging [redacted] and [redacted] respectively. Current FDA guidelines for vacuum-packaged smoked fish (without nitrites added) recommends a consistent water phase salt level of 3.5% or higher to achieve an effective barrier against pathogenic bacteria growth. This level is lower for air-packaged smoked fish without nitrites added, and is recommended at 3.0% or higher. We urge your firm to reassess your brining method and develop a method that ensures consistent levels of water phase salt in your vacuum-packaged fish of 3.5% or higher. Factors to consider when developing your brining procedure are appropriate salt level, consistent batch sizes and uniformity of brined pieces (thickness), adequate time of fish pieces in the brining solution, and temperature. All of these factors can affect the amount of salt that

penetrates the fish muscle. The brining procedure is a critical control point in your firm's operations, and must be documented to ensure it is performed correctly and consistently.

The Report of Sample Analysis also details histamine analysis of the two samples. Both of these samples found high levels in some of the pieces. The smoked tuna sample (#29791) found histamine levels at least [redacted] in five of nine subsamples analyzed. Two of the nine subsamples found histamine levels of [redacted] on check analysis. The smoked yellowtail sample (#29792) found similar results when analyzed; four of seven subsamples found histamine levels [redacted] ppm upon initial analysis, and two of four found [redacted] on check analysis. One subsample (17) found histamine levels on original analysis of [redacted] and [redacted] on check analysis.

High levels of histamine in fish can cause severe allergic reactions to histamine sensitive individuals. It appears that your source controls could allow for compromised fish to enter and be processed by your facility. It is incumbent of your firm to assure that the scombroid fish you receive has no histamine or acceptable levels of histamine prior to acceptance of these raw materials, and that you do not add or increase the level of histamine in fish at your plant through time/temperature abuse.

Pertinent sections of the Act and the Regulations are enclosed for your review. Your reply relating to these concerns should be directed to the Food & Drug Administration, Los Angeles District, Attention: Robert B. McNab, Consumer Safety Officer, 19900 MacArthur Blvd, Ste. 300, Irvine, CA 92612-2445.

Sincerely,

Elaine C. Messa

Elaine C. Messa
Los Angeles District Director

Enclosures
1. FORM FDA 483
2. FORM FDA 483
3. Section 402 of the Act
4. Section 403 of the Act
5. 21 CFR Part 123
6. FORM FDA 1551
7. FORM FDA 1551
8. FR 2/24/97, Guidance on Labeling of Foods That Need Refrigeration.

cc: State of California Department of Health Services
601 North 7th Street
Sacramento, CA 94234-7320
Attn: Stuart Richardson